C. Remarks

Applicants wish to thank Examiner for granting a telephone interview on March 25, 2004 in which Applicants' further presented their points of novelty in the present invention.

Claims 1-21 and 23-38 are pending in the application. Claim 1 has been amended. The claim amendment is offered free of any intent to narrow the scope of what Applicants' consider as their invention. Support for the amendments may be found throughout the specification as filed, including the documents and references cited and incorporated therein.

Claims 1-21 and 23-38 stand rejected under 35 USC § 103(a) as being unpatentable over Garbe et al. (WO 96/08229) in view of Cleary (EP 0483105 A1). The rejection is respectfully traversed. Reconsideration and withdrawal of this rejection is requested.

The Office Action cites statements made in a prior office action, and reiterates, in part: The Garbe reference teaches a transdermal drug delivery device compromising a backing and a matrix comprising a copolymer, a softener and a drug. The copolymer in the Garbe reference comprises one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group; one or more ethylenically unsaturated B monomers copolymerizable with the A monomers and a macromonomer copolymerizable with the A and B monomers. The macromonomer in the Garbe reference is generally present in an amount of 0.1 to 30% by weight based on the total weight of all monomers in the copolymer. The Examiner indicates that the Garbe reference does not expressly disclose the exact concentration ranges in the instant claims nor does it teach specifically that fentanyl in the drug delivered. The Cleary reference teaches a transdermal delivery device comprising fentanyl and absorption enhancers in a matrix which are fatty acid esters or fatty alcohol ethers.

As stated in the Examiner interview, given the well-known difficulties associated with solubilizing fentanyl, even if one had been motivated to use a higher concentration of the drug, there would have been no expectation of success or reason to make a change by incorporating fentanyl into the Garbe device in the amounts recited in the present claims while still providing a

composition that was substantially free of undissolved drug. Additionally, Garbe is directed to devices comprising a softener, which is referred to as a generally oily material. The scope of Garbe does not encompass compositions containing drug and copolymer without the presence of a softener. Fentanyl is not an oily or liquid material. The teaching within Garbe regarding fentanyl would lead one to make a device containing a softener, and thus teaches away from a composition consisting essentially of copolymer and fentanyl (i.e., having no softener).

Cleary (EP 483105 A1) does not remedy this deficiency, as it only teaches delivery of fentanyl in conjuction with a percutaneous penetration enhancer that is a fatty acid ester or fatty alcohol ether of a C_2 to C_4 alkanediol. Furthermore, the Cleary reference fails to demonstrate any ability to dissolve fentanyl at high concentrations in transdermal devices.

In view of the arguments and amendments offered herein, Applicants respectfully submit that the Examiner's grounds for rejection are overcome and respectfully solicit reconsideration and withdrawal of the rejections and allowance of the application.

Respectfully submitted,

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